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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,596	08/13/2001	Todd K. Whitehurst	AB-125U	9185

23845 7590 09/12/2003

ADVANCED BIONICS CORPORATION
12740 SAN FERNANDO ROAD
SYLMAR, CA 91342

EXAMINER

MACHUGA, JOSEPH S

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,596

Applicant(s)

WHITEHURST ET AL.

Examiner

Joseph S. Machuga

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 12, 13, 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The noted claims are indefinite. Claim 2 states that the pulses are delivered at a frequency greater than about 50-100 Hz. It is unclear whether numeric values between 50 and 100 would meet these criteria. Also the term "about 50" is vague. For example, 35, 40 and 45 are about 50 if the reference range is 0-1000. Similar problems exist in claims 12, 13, 22 and 24.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 1-6, 8-17, 19-23, 27, 30, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho et al (4703755) in view of Schulman et al (5193540.)

5. Tanagho et al discloses a method and device for controlling bladder function.

The device includes a multiple electrode stimulators. The electrodes are implanted near the S2, S3 and S4 nerves and provide inhibitory stimulation pulses in the range of 5 to

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40 Hz to control incontinence and 15 to 50 Hz to begin evacuation of the bladder. Power and stimulation parameters are provided from an external component. Not disclosed by this reference is the step of providing stimulation parameters to the stimulator and generating stimulating pulses in accordance with the parameters.

Schulman et al discloses an implantable micro stimulator having electrodes, rechargeable power supply and a control circuit integrated into a single compact implantable unit. Control instructions/parameters and batteries recharging is provided by an external interface. This arrangement provides a device that can be easily implanted into a patient through a hypodermic needle. The reference also teaches that multiple micro-stimulators can be used.

It would have been obvious to one of ordinary skill in the art to make Tanagho et al's device as a self contained implant having a rechargeable battery and control circuits given Shulman et al's disclosure that this is old and well known in the art to do so and provides a system that is simpler to implant. This obvious modification would provide the method steps of providing operating power and providing stimulating parameters to the stimulator and generating the stimulation pulses as required by the claims. To use multiple micro-stimulators to add control over other adjacent nerves such as the S2 and S4, (nerves also known to also influence bladder function) would also have been obvious given Shulman et al's disclosure. Regarding claim 2, the reference to Tanagho et al teaching providing pulses at a frequency of 5-40 Hz. To raise that value to 50 or 55 is considered an obvious variation since it is well known in the art that the effective ranges vary slightly from patient to patient and on the actual location of the implant.

Also, in a broad interpretation of the claim language "39" is considered "about 50" given that frequencies of 120hz, 200hz up to 1000hz are seen in the prior art devices. Under such an interpretation, Tanagho et al would provide for the claimed limitation.

Claim 7, 18, 25, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho et al in view of Schulman et al as applied to claim 1 above, and further in view of Lin (5833595.)

Lin discloses a device for controlling bladder function. The reference teaches monitoring the pressure in the bladder and to use those measurements to alter the level of stimulation applied to the nerves. This assures that excessive bladder pressure is not reached in the patient. The reference also teaches stimulating the nerves of the L1 to S5 vertebrae to control bladder function. Given Lin's teaching it would have been obvious to one of ordinary skill in the art to provide a monitor for bladder pressure in the implant of the proposed combination and use the data received to adjust the stimulation levels of the implant to avoid excessive bladder pressure in the patient. To stimulate the nerves of the L1 or L2 vertebrae would also have been obvious given Lin's teaching that those locations also influence bladder function.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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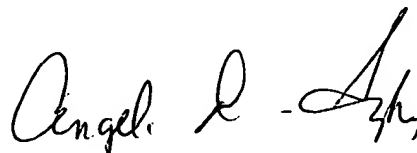
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Joseph S. Machuga
Examiner
Art Unit 3762



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700